K083178

## 5. 510(k) Summary

The following information is being submitted in conformance with 21 CFR 807.92(c):

Manufacturer:
Biotechni America Spine Group, Inc. (BASG, Inc)
28R Cook Street
Billerica, MA 01821
Tel.: (617) 308-4500
Fax: (978) 663-4364

FEB 23 2009

Contact: David S. Randol, Director

Date Prepared: October 3, 2008

Trade Name: SOLAS AnatomixTM Spinal System

Common Name: Pedicle Screw Spinal System

Classification: Spinal Intervertebral Body Fixation Orthosis (KWQ) (21 CFR § 888.3060)
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3855)
Spinal Pedicle Screw (MNI) (21 CFR § 888.3070)
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3900)
Spondylolisthesis Spinal Fixation Device System (MNH) (21 CFR § 888.3070)
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3899)

Legally Marketed Predicate Devices for the Application:
NV Cormed, SOLAS™ Spinal System –MNH, KWQ, MNI – (K051959)
Micron Precision Engineering, AMT Spinal System – KWP, MNH -- (K002059)
Stryker® Spine, XIA™ Spinal System -- MNH, MNI, KWQ -- (K001319)

Device Description:
The *SOLAS Anatomix* Spinal System is a new modular spinal fixation system which can be used for anterior, antereolateral, posterior applications. This system includes screws, housing assemblies, rods, connectors and a cross-link mechanism in conjunction with specialized instruments which facilitate application. All implant components are fabricated from Titanium alloy that conforms to ASTM F 136.

Intended Use:

The BASG, Inc., SOLAS AnatomixTM, Spinal System is a modular pedicle screw based spinal fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the SOLAS Anatomix™ is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

The SOLAS Anatomix™ is intended for anterior/anterolateral and posterior, non-cervical and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture and/or dislocation) spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Technological Characteristics – Comparison to Predicates:
The subject spinal implant system is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use, and operational principles. The differences between the application device and the predicate devices do not change the indications, nor does the method of implantation.

Performance Data – Comparison to Predicates:
Performance testing followed the instructions and recommendations in the CDRH document: "Guidance for Industry and FDA Staff: Spinal System 510(k), May 3, 2004 (www.fda.gov/cdrh/ode/guidance/636.pdf). Mechanical testing results conducted via ASTM F1717-04 demonstrated equivalence to the above listed predicate devices and is detailed in the body of the application. Table 5.1 on next page summarizes the required testing and comparisons.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biotechni America Spine Group, Inc.
% Kinetic Research & Design, Inc.
Daniel R. Baker, Ph.D.
13203 39th Avenue, NE
Seattle, Washington 98125

FEB 23 2009

Re: K083178
Trade/Device Name: BASG, Inc., SOLAS Anatomix™, Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWQ
Dated: January 21, 2009
Received: January 27, 2009

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

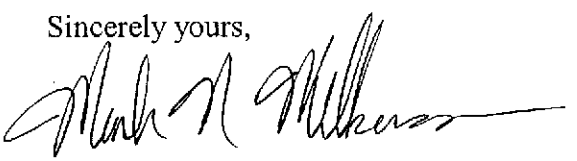
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. INDICATIONS FOR USE

**510(k) Number (if known):** K083178.

**Device Name:** BASG, Inc., *SOLAS Anatomix™*, Spinal System

**Indications for Use:** The BASG, Inc., SOLAS AnatomixTM, Spinal System is a modular pedicle screw based spinal fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use __X___ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083178